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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,399

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Henry William Lupton

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

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DELIVERY MODE

11/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/539,399	LUPTON, HENRY WILLIAM	
	Examiner	Art Unit	
	John Pani	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/16/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 51-60, 66, and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Regarding claims 51, 52, 55, 57-60, 66 and 67, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
4. Claims 53, 54, and 56 are indefinite because they depend from an indefinite base claim.
5. Claim 60 is indefinite because the use of the term "or" in line 2 is followed by "alternatively the opposite longitudinally...extending ridge" of lines 3-5 and "and preferably...reinforcing member" of lines 6-7. It is unclear whether the claim is attempting to require either "that the opposite...are parallel to each other" of lines 1-2 *or* the prior recited lines 3-5, *and* additionally require the phrase of claims 6-7; or attempting to require the phrase of lines 1-2 *or* both that of lines 3-5 *and* that of lines 6-7. This renders the claim indefinite.

NOTE: For purposes of rejections based on prior art, claim limitations following the term "preferably" have been interpreted as optional structures that are not required by the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 50-65, 68, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 7,083,577 to Osawa et al ("Osawa").

8. Osawa teaches:

In reference to Claims 50 and 68

A guide wire (1) and a distal portion (distal tip embodiment of Fig. 5A) for a guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject (col. 1 lines 5-7), the guide wire defining a longitudinally extending axis (See Fig. 10), and terminating at one end in a proximal portion (proximal end Fig. 10), and at an opposite end in a distal portion (23) for accessing the remote site, the distal portion terminating adjacent a distal end thereof in a guide portion (thin, central flat portion in Fig. 5A), the guide

portion being adapted to be shaped to a desired curved configuration for facilitating guiding of the guide wire into a branched vessel of the subject (see col. 7 lines 31-40), characterized in that a reinforcing means (raised sections **232**) is provided on the distal portion for minimizing axial twisting of the distal portion between a proximal end of the distal portion and the guide portion thereof (see col. 4 lines 50-65).

In reference to Claim 51

A guide wire as claimed in claim 50 (see above) characterized in that the reinforcing means is an elongated reinforcing means having a proximal end and a distal end, the reinforcing means extends along at least a portion of the distal portion between the proximal end of the distal portion and the guide portion (See Fig. 5A), and the distal end of the reinforcing means is spaced apart (radially, see Figs. 5A-5B) from the distal end of the distal portion of the guide wire and defines with the distal end of the distal portion of the guide wire the guide portion thereof.

In reference to Claim 52

A guide wire as claimed in claim 51 (see above), characterized in that the reinforcing means extends from the proximal end of the distal portion and the proximal end of the reinforcing means substantially coincides with the proximal end of the distal portion of the guide wire, and the reinforcing means extends in a generally axial direction (see Fig. 5A).

In reference to Claim 53

A guide wire as claimed in claim 51 (see above) characterized in that the distal portion of the guide wire defines a longitudinally extending flat surface (thin flat portions in Fig. 5A), and the reinforcing means extends along the flat surface and from the flat surface terminating in a longitudinally extending edge (the long edges of the raised surfaces **232**).

In reference to Claim 54

A guide wire as claimed in claim 53 (see above) characterized in that the distal portion of the guide wire is of rectangular transverse cross-section (See Fig. 5C) defining a pair of opposite major flat surfaces (the thin, flat surfaces that angle inward in Fig. 5B, and are shown face on in Fig. 5C), joined by a pair of opposite minor surfaces (the top surface shown in Fig. 5B, and matching bottom surface), the major flat surfaces defining a central major plane located midway between the major surfaces, and the minor surfaces defining a central minor plane located midway between the minor surfaces, the reinforcing means located on one of the major flat surfaces (see Figs. 5A-5C).

In reference to Claim 55

A guide wire as claimed in claim 54 (see above) characterized in that the reinforcing means is located on both of the major flat surfaces and the respective major flat surfaces converge towards each other towards the distal end of the distal portion (Figs. 5A-5C).

In reference to Claim 56

A guide wire as claimed in claim 54 (see above) characterized in that the transverse distance of the longitudinally extending edge of each reinforcing means from the central major plane is substantially constant along the reinforcing means (see Fig. 5B).

In reference to Claim 57

A guide wire as claimed in claim 54 (see above) characterized in that each reinforcing means extends parallel to the central minor plane (i.e. radially) and each reinforcing means coincides with the central minor plane (see Fig. 5A).

In reference to Claim 58

A guide wire as claimed in claim 54 (see above) characterized in that each reinforcing means extends at an angle greater than zero degrees to the central minor plane (the raised surfaces have extensions at various non-zero angles with respect to the central minor plane), and each reinforcing means extends adjacent one of the minor surfaces (slanting edges approach minor surfaces), and one reinforcing means extends from each of the major flat surfaces, one of the reinforcing means extending adjacent one of the minor surfaces, and the other reinforcing means extending adjacent to the other minor surface (both reinforcing means have extensions that approach each of the minor surfaces).

In reference to Claim 59

A guide wire as claimed in 51 (see above) characterized in that each reinforcing means comprises an elongated reinforcing member (axially elongated), and each reinforcing member defines opposite longitudinally

extending sides (flat portions depicted in Fig. 5C), and the opposite longitudinally extending sides of each reinforcing member terminate along the longitudinally extending edge thereof (see Fig. 5C).

In reference to Claim 60

A guide wire as claimed in claim 59 (see above) characterized in that the opposite longitudinally extending sides of each reinforcing member are parallel to each other (see Fig. 5B).

In reference to Claim 61

A guide wire as claimed in claim 50 (see above) characterized in that each reinforcing means is integrally formed with the distal portion (see Fig. 5A) and each reinforcing means and the distal portion are of metal (see col. 7 lines 20-50). Nothing about the structure precludes that they could be formed from forging from a single piece of metal or by rolling from a single piece of metal.

In reference to Claim 62

A guide wire as claimed in claim 50 (see above) characterized in that the distal portion of the guide wire extends through a sleeve (3), and a first securing means (4) at the distal end thereof secures the distal portion to the sleeve, the first securing means defining the distal end of the guide wire (see Fig. 10).

In reference to Claim 63

A guide wire as claimed in claim 62 (see above) characterized in that the first securing means is shaped to form a dome shaped distal end (see Fig. 10) for facilitating passage of the guide wire smoothly through a vessel of the subject.

In reference to Claim 64

A guide wire as claimed in 62 (see above) characterized in that the guide portion is located between each reinforcing means (see Fig. 5A) and the first securing means (The distal tip is melted to the securing means, thus the guide portion, which includes the flat portion as it extends across between the two reinforcing members would be between both of the reinforcing means, and portions of the securing means that were on either side of it, particularly when viewed head on from the distal end of the guidewire, see col. 7 lines 60-67 and Fig. 10).

In reference to Claim 65

A guide wire as claimed in claim 62 (see above) characterized in that the first securing means comprises a solder joint, an adhesive joint, or a brazed joint (see col. 7 lines 58-60).

In reference to Claim 69

In combination a catheter (see col. 1 lines 5-7) and the guide wire as claimed in claim 50 (see above).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osawa.

11. Osawa teaches the guide wire as claimed in claim 50 (see above), and further is characterized in that the guide wire is substantially torsionally rigid between the distal portion and the proximal portion of the guide wire for minimizing axial twisting of the guide wire between the proximal portion and the guide portion (see col. 4 lines 50-65) and that a portion (22) of the guide wire adjacent the distal portion tapers towards the distal portion, but the embodiment of Fig. 10 is made of two pieces of material. The embodiment of Fig. 2 is formed from a single piece of material. It would have been obvious to one having ordinary skill in the art to have modified Osawa by producing a guidewire that was formed from a material to be easily preshaped, as taught in the embodiment of Fig. 10, while producing the guide wire from one piece of material, as taught by the embodiment of Fig. 2, in order to simplify the manufacturing process while producing a guide wire that could be preshaped, as taught by Osawa.

12. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osawa in view of US Pat. No. 5,135,503 to Abrams ("Abrams").

13. Osawa teaches the guide wire as claimed in claim 62 (see above) characterized in that the sleeve extends beyond the proximal end of the distal portion along a portion of the guide wire (see Fig. 10), and that a proximal end of the sleeve is secured to the guide wire by a second securing means that comprises an adhesive joint, solder joint, or a brazed joint (see col. 7 lines 55-60), and that a portion of the sleeve Adjacent the distal end of a radiopaque material (see col. 8 lines 5-10), and that the sleeve is a tightly

wound coiled spring of a metal material (see col. 8 lines 10-15) and that a portion of the sleeve is made from platinum, gold, or tantalum. However, Osawa does not teach that the sleeve is secured to the guide wire at at least one intermediate location intermediate the proximal end and distal end of the sleeve using an intermediate securing means of an adhesive joint, solder joint, or brazed joint. Abrams teaches of a guide wire which includes an intermediate securing means **23** of brazing or soldering (see col. 3 lines 32-36). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Osawa by including an intermediate securing means by brazing, as taught by Abrams, in order to achieve the predictable result of attaching an outer coil/sleeve to the inner wire of a guide wire.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JP 11/20/07


MARK H. DENEHY
ELECTRONIC BUSINESS CENTER
U.S. PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20503